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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,567	03/07/2002	Jonathan P. Wong	NEL-006	7851

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EXAMINER	
HILL, MYRON G	

ART UNIT	PAPER NUMBER
1648	20

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	10/091,567	WONG ET AL.	
	Examiner	Art Unit	
	Myron G. Hill	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *19 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8- 12, 14, 15, and 17- 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8- 12, 14, 15, and 17- 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/10 and 19/2003 has been entered.

Claims 8- 12, 14, 15, and 17- 19 are under consideration.

Declaration of J. P. Wong

The declaration has been fully considered and found persuasive in part.

The remarks concerning the Promega catalog are not considered to address the issue under consideration. The statement that the invention liposomal encapsidation is far superior to that of Sha *et al.* is not entirely demonstrated because the two compositions were not tested side by side.

The declaration does not fully differentiate between the liposomes of Sha *et al.* and the invention other to say that the invention liposomes are encapsidated and the Sha *et al.* are complexes. It is not clear how this invention forms complexes that differ from the prior art. This is discussed below.

Rejections Withdrawn

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 10 and 11 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn because Applicant has amended the claim to recite a product.

The rejection of claims 10 and 11 under 35 U.S.C. 101 is withdrawn because the claims were amended to recite a product.

Rejections Maintained

Claim Rejections - 35 USC § 102

Claims 8- 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Sha *et al.*

Sha *et al.* teaches a DNA vaccine using an influenza HA gene that is encapsulated in liposomes and that it produces a mucosal immunity as show by the IgA antibody response (pages 21- 22Figure 1, page 27 last paragraph- page 28, first paragraph).

Applicant argues that the liposomes taught by Sha *et al.* are not the same as the present invention and that the composition of Sha *et al.* did not work, that Applicant is

not required to limit the formulation when it can be determined from the specification, that the plasmid of the invention is encapsidated in a in liposomes and are of a different design, that the Examiner is taking Official Notice, and that Sha *et al.* invite further experimentation and do not provide anticipation.

The arguments have been fully considered and not found persuasive.

The limitation of specific liposomal formulation is not in the claims. The claims are not drawn to specific liposome compositions but to a polynucleotide vaccine. Applicants state they do not have to limit the claims but go on to argue that their liposomes are different. The difference is not recited in the claims and the claims can be interpreted in light of the specification but are not limited to what is disclosed in the specification. The examiner is not taking Official Notice but uses what is taught in Sha *et al.* The declaration shows that this encapsidation works but the declaration does not teach or disclose that the composition of Sha *et al.* will not work when tested by the same method. As discussed in the previous rejection, *Sha et al.* give specific reasons for the failure of their experiment

Because the vaccine of Sha *et al.* did not protect IM, the method claims are withdrawn from the rejection because they are not anticipated. The rejected claims are drawn to a product that is taught by Sha *et al.* The difference between the invention and Sha *et al.* liposomes are not in the claims.

Thus, Sha *et al.* anticipate claims 8- 11.

Claim Rejections - 35 USC § 103

Claims 8, 12, 14, 15, and 17- 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sha *et al.* and Promega Catalog.

Applicant argues that the Promega catalog does not compensate for the deficiencies of Sha *et al.* and that the composition of Sha *et al.* is a complex and not encapsidated.

The arguments have been fully considered and not found persuasive. As discussed above, the claimed product encapsidated by liposomes has all the properties of the prior art liposomes. One of ordinary skill in the art at the time of invention would have been motivated to use the plasmid of the Promega catalog because it teaches that the plasmid expresses constituatively in mammalian cells and teaches that the plasmid can be transfected with cationic lipids. Also, both the plasmids of Sha *et al.* and Promega use the same promoter and are equivalent in that respect. While the exact formulation and steps are not taught, the same steps are used as taught in the prior art. A lipid solution is made, dried and resuspended. DNA is added to the resuspended lipid to form complexes. Both the prior art and this invention use that step.

The cited prior art does not teach dialyzing the sample or removing the unbound DNA.

The specification and declaration both state for IM inoculation, that pCI-HA 10 either naked or in liposomes, induce protection. One of ordinary skill in the art would not see that this changes the product or confers additional properties. Furthermore, this step removes unbound DNA, it is not stated or disclosed that the purified liposomes are

in fact encapsidated or that the step differentiated between liposomes. This step only removes unbound DNA. In preparation of DNA for transfection, it is diluted with amount of media or buffer and dialyzing against buffer is an equivalent step in that it serves the same purpose. DOPE based transfection reagents are known in the art.

Because both lipid formulations are mixed with DNA in the same manner, both must be encapsidated in the same way.

Sha *et al.* disclose that their experiment did not protect the mice against challenge. They disclose that their method of challenge bypassed the mucosal antibodies that were induced by their vaccine, that liposomes are known to induce good mucosal immunity with DNA vaccines, that the levels of neutralizing antibody produced by Sha *et al.* were high, and that the antibody levels induced by the vaccine were similar to those induced by cholera toxin (page 28, Table 1, and Figures 1 and 2).

The specification discloses in Figure 5 IgA titers. No direct comparison can be made between Sha *et al.* and Figure 5. However, one of ordinary skill in the art at the time of invention would have realized that the levels were significant because cholera toxin is known to be very immunogenic and induce mucosal immunity.

Thus, claims 8, 12, 14, 15, and 17- 19 are unpatentable over Sha *et al.* and the Promega Catalog.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Myron G. Hill
Patent Examiner
March 22, 2004

James C. Housel 3/22/04
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